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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,431	04/04/2001	Jerome J. Cuomo	5051-511	8488

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EXAMINER
TRAN, MY-CHAU T

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/826,431	Applicant(s) CUOMO ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1641	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *33-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☒ Claim(s) *32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32, drawn to a substrate, classified in class 435, subclass 4.

II. Claims 33-43, drawn to a chemical method, classified in class 428, subclass 405.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of group I and group II are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for making the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of making that product (MPEP § 806.05(h)). In the instant case the product as claimed can be made in a materially different process such as conventional electrodeposition.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Robert J. Smith on October 24, 2001 a provisional election was made without traverse to prosecute the invention of group I, claims 1-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims

33-43 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claim 32 objected to because of the following informalities: Claim 32 is dependent on itself. Claim 32 should be dependent on claim 31. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The claim 1 term "chemically modified surface" renders the claim indefinite since it does not particularly point out how the surface is "chemically modified". A "chemically modified surface" can refer to a painted surface, which is not supported by

the specification. Although the "substrate" is required to have a "coating" and a terminal "functional group", it is not clear whether the presence of these components constitutes the chemical modification or whether an additional (unspecified) modification is intended.

b) It is unclear what is meant by the claim 1 term "a base layer" and "a substrate". The claim fails to define a field of use for the "substrate" and the characteristics, which are required for the "base layer" and "substrate" to be useful for the practice of the invention. A "base layer" could refer to a sheet of aluminum or a piece of paper, which are not supported by the enabling written description in the specification.

c) It is unclear what is meant by the claim 1 term "a chemically crosslinked material". Given the scope encompassed by the definitions (1)-(4) it cannot be determined exactly what is included by the claim. A "chemically crosslinked material" as defined by (1)-(4) can refer to a polymer such as polystyrene or polyethylene glycol, carbon in the form of diamond (definition (3)), RNA (definition (1)), or a polypeptide (definition (4)). Further, it is not clear what type of "chemically crosslinked material" as defined by (5) could be prepared ***solely*** from (a) carbon and oxygen, (b) carbon and nitrogen, or (c) carbon and hydrogen as required by definition (5).

d) Claim 21 is indefinite in the use of the term "a detection system" since it is unclear what elements are required in addition to the "substrate" of claim 1. For claim 22, it is unclear whether the recited "detection systems" are meant to include actual instruments such as fluorometers and UV detectors.

e) Claim 31 is indefinite in the use of the term " a microfluidic system" since it is unclear what components are required in addition to the "substrate" of claim 1.

f) In claim 32, it is unclear what is meant by the term "at least one biofouling surface". Additionally, the specification fails to describe this term.

g) In claim 17, it is unclear what is meant by the term "a monolayer thick". Page 4, lines 17-22 of the specification describe a "monolayer" but this term is used to define an ***area*** rather than a ***thickness***.

h) In claim 3, there is no antecedent in claim 1 for the term "chemically crosslinked composition".

Claims 2-32 depend from rejected claim 1 and include all of the limitations of claim 1 thereby rendering these dependent claims indefinite.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process disclosed by example 1, does not reasonably provide enablement for the scope encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. How is the surface made and use in a detection system? Where would this surface be use in a microfluidic system? Is the surface found in the reaction vessel or the flow path? Is the surface use in preparation or

purification of viruses, enzymes, DNA, or proteins? How does it work? Is the surface part of an assay?

The enabling disclosure described by the process of example 1 in the written description is inadequate and non-enabling for the entire scope of the claims. The specification provides an enabling written description ***limited to*** a "substrate" produced by the process of Example 1 using the specific components of Example 1. However, it is unclear how the "passivation layer" may be related to the layers described in claim 1. The specification fails to provide an adequate enabling written description of and support for each the terms set forth in paragraphs a) through h) above.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorp et al. (U.S. Patent 5,968,745).

Thorp et al. teaches a polymer-electrode (detection system) for detecting nucleic acid hybridization (Abstract; col. 3, line 9-17; fig.1), which anticipates the substrate of instant claim 1. The polymer-electrode consists of a substrate (base), a polymer membrane (coating), and an oligonucleotide probe (functional group). The features of the dependent claims are specifically described by the reference. For example, for the silicon substrate of claim 2 see col. 5, line 10.

For the electrophilic group of claim 4 see col. 6, line 10-14. For the nucleic acid biomolecule of claim 7 see col. 4, line 48-50. For the intermediate layer of claim 19 sees fig. 1 (conductive working surface). For the indium tine oxide (ITO) of claim 20 see col. 5, line 11-16.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorp et al (U.S. 5,968,745) taken in combination with Heller et al (U.S. 5,632,957).

Thorp et al is applied for the reasons stated in the above 35 USC 102 rejection. The composition of Thorp et al is not specifically described as being used in a "micro" format i.e. in a format that uses small quantities of reactants rather than larger quantities.

Heller et al establishes that it is well known in the art to perform assays on a "micro" scale. Heller et al. discloses a molecular biological diagnostic system (microfluidic system) (Abstract and col. 4, line 48-52). This system can actively carry out controlled multi-step processing and multiplex reactions in a microscopic formats. It would provide an effective technique to conduct multi-step, multiplex molecular biological reactions (col.4, line 37-39). The active programmable electronic matrix hybridization system (fig. 2A and 2B) of the

molecular biological diagnostic system is consisting of an electrode (base), a permeation layer (coating), and an attachment layer (functional group) (fig. 5 and col. 10, line 5-9).

In view of the fact that it is well known in the art that diagnostic assays can be performed either on a "macro" scale (Thorp et al) or on a "micro" scale (Heller et al), it would be obvious to use the composition of Thorp et al in a "**micro**fluidic system" (as in Heller et al), as claimed, with the expectation of obtaining a system which would be useful when limited amounts of assay reagents are available.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
November 8, 2001

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
ART UNIT ~~122~~ 1641